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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/807,500	02/27/1997	MARC ZEICHER	236007	5090

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EXAMINER	
MCGARRY, SEAN	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 09/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/807,500	ZEICHER, MARC	
	Examiner	Art Unit	
	Sean R. McGarry	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-16,21,22 and 28-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-10,13-16,21,22 and 28-30* is/are rejected.

7)☒ Claim(s) *11 and 12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application was suspened in view of a potential interference. However, upon further review of the translated priority document, Belgium 09201087, it was found that support was not provided in that reference for many limitations in the instant claims and a new Action is issued. The reference fails to provide support for the following: Claim 3 – "LuIII" parvovirus, Claim 8 - "IRES", Claim 9 – "hypervariable end of an antibody", "cytokine", "growth factor", "fusion peptide" (wherein the preceding specifically bind to a molecule expressed on the surface of cancerous or infected cells), Claim 10 – a peptide that "increases an immune response", a "polypeptide which inhibits tumor neoangiogenesis", Claim 13 – "interferon-alpha", "interferon-beta", and "platelet factor 4", Claim 14 – "an RNA, which destroys or normalizes cancer or infected cells", Claim 15 – "antisense RNA or a ribozyme" (It is noted that the priority document provides support for only a ribozyme that specifically targets a gene of CMV), Claim 21 – "a mixture thereof", and Claim 28 – "polypeptide which increases an immune response". Accordingly only claim 11 and 12 are granted a priority date of the priority document. The remainder of the claims are granted a priority date that is the date of the instant application filing. If applicant believes that the priority document provides support for the above limitations in the context of the instant claims applicant should point out such support with particularity.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 3-7, 9, 10, 14-16, 22, 28, and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Maxwell et al [US Patent No. 5,585,254].

Maxwell et al disclose autonomous Parvoviral gene delivery vehicles and expression vectors. The autonomous vectors include LuIII, MVMi, MVMp, and H1, for example. These vectors are disclosed to express compounds such as antisense RNA, ribozymes, RNA-based drugs, and cytotoxic proteins (including cytokines (see column 11) modified (see column10)), and immunopotentiating agents (see column 4, for example). It is disclosed that 90 percent of an autonomous parvovirus can be modified to produce a desired heterologous vector and NS and VP gene can *optionally* be kept in

a vector for desired characteristics. Embodiments that show no P38 promoter sequence and no NSI, and also embodiments where A promoter other than p4 is inserted between the regions defined as P4 and NSI in a parvoviral vector are disclosed in at least figures 1-4 , for example It is disclosed that any cis acting nucleic acid sequence from which polymerase can be used to initiate transcription and "response element" can be included in the vector. It is disclosed that control elements and coding regions can be combined in a variety of ways (see column 10, last full paragraph, for example). It is further disclosed that a "cell-selective response element can be include and include, for example, elastase I enhances, and HIV response elements such as TAR. It is also disclosed that virus particles can be produced that selectively target desired cell types (see column 18, for example). It has been disclosed plural heterologous coding nucleic acids can be included in the vectors of the invention (see column 10, lines64-67, for example. See claims 1-81 Maxwell, for example.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7, 8, 13, 21, and 28, 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maxwell et al [US Patent 5,585,254]. Applicants arguments are addressed below.

The instant invention is drawn to a parvoviral vectors that include; 1) an IRES nucleotide sequence, a sequence encoding interferon- , interferon- , or PAF-4. 4) the specific promoters/enhances recited in claim 21.

Maxwell et al have taught autonomous Parvoviral gene delivery vehicles and expression vectors. The autonomous vectors include LuIII, MVMi, MVMp, and H1, for example. These vectors express compounds such as antisense RNA, ribozymes, RNA-based drugs, and cytotoxic proteins and immunopetentiating sequences such as lymphokines, interleukins and cytokines. It has been taught that 90 percent of an autonomous parvovirus can be modified tp produce a desired heterologous vector and NS and VP gene can *optionally* be kept in a vector for desired characteristics. It has been taught that any cis acting nucleic acid sequence from which polymerase can be used to initiate transcription and "response element" can be included in the vector. It has been taught that control elements and coding regions can be combined in a variety of ways (see column 10, last full paragraph, for example). It has been taught plural heterologous coding nucleic acids can be included in the vectors of the invention (see column 10, lines64-67, for example). Further it has been taught that a "cell-selective response element" can be include and include, for example, elastase I enhancers, and HIV response elements such as TAR. It is also disclosed that virus particles can be produced that selectively target desired cell types (see column 18, for example). Maxwell et al have not specifically taught the specific limitations listed above. However, the specific limitations recited in the instantly rejected claims do not define the instant invention over the prior art. Maxwell et al have taught the general concepts in the construction of parvoviral vectors where the specific limitations are embraced within

those teachings. Maxwell have provided several examples for specific embodiments of expression products such as antisense RNA, ribozymes, RNA-based drugs, and cytotoxic proteins and further has taught that control elements and coding regions can be combined in a variety of ways where promoters are suggested and exemplified. The instant limitations would be a matter of routine choice in the choosing of specific promoters, enhancers and desired expression products. The limitations instantly recited are members of the promoter, enhancers and expression products that could have been used in the parvoviral vectors described by Maxwell et al, where the instant limitations represent promoters, enhancers, expression products and "response elements" that were known in the art at the time of invention and were routinely used in the art at the time of the instant invention (see column 9 and column 10, 3rd full paragraph, for example). The instant specification does not indicate any unexpected results with the use of the specific element recited in the instant claims, for example. There would have been an expectation of their successful application since Maxwell et al have described correlative limitations in their parvoviral vectors.

The invention as a whole would therefore have been *prima facie* obvious to one of ordinary skill in that art at the time the invention was made.

Claims 11 and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R. McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sean R McGarry
Primary Examiner
Art Unit 1635